

Plant protection – Regulatory affairs

Regulation 1107/2009 was published in 2009 and entered into force in June 2011. This replaced Directive 91/414/EEC. The Regulation sets out, amongst other things, the requirements for placing plant protection products on the EU market and introduces many new regulatory challenges. Importantly, the Regulation sets out comprehensive approval criteria for active substances at the EU level and new procedures for product assessment within a zonal authorisation framework.

The Regulation also provides the basis for an ambitious and comprehensive renewal programme for existing approved active substances (the 'AIR' programme). New data requirements for active substances and products have also been established and there is a continuing programme for establishing new technical and procedural guidance.

How TSG can help ⇐

TSG has a proven record of achieving numerous successful regulatory outcomes with applications for new active substances and renewals of existing active substances (the latter under the AIR programmes). We are experienced in all types of product authorisations (renewals under Art. 43, zonal applications under Art. 33, national authorisations and mutual recognitions). We have extensive experience in dealing with regulators and with our network of regional offices, we continue to provide an extensive EU-wide product registration service.

Our services include ⇐

- Strategic advice and guidance
- Data Gap Analysis
- Preparation of dossiers for new and existing active substances
- Preparation of product dossiers (dRRs)
- Adding new uses to existing product approvals
- Preparation and review of product labels
- Preparation of Biological Assessment Dossiers
- Preparation of MSDSs
- Task force management
- Human health and environmental risk assessments including national risk assessments where required
- Study design and monitoring
- Preparation of expert reports/waivers
- Liaison with regulatory authorities
- Training
- Due diligence audits
- Conducting EFSA compliant literature search and review, plus production of a literature report





TSG's expertise gained from industry, government and research allows us to provide effective support and guidance for ensuring and gaining regulatory compliance for active substances and plant protection products.

We believe in the value of proactive project management to control cost, manage deadlines and communicate with our clients in a professional and timely manner. Supported by our multidisciplinary team of scientists and registration specialists, we are able to provide a comprehensive service to the plant protection industry.

About TSG

For almost 30 years, TSG Consulting has provided companies around the world with regulatory guidance and scientific expertise. Our experts are highly knowledgeable in the core sciences and the public policy decisions that are used to structure and implement environmental and chemical regulations. By combining this knowledge with our industry experience, we provide companies with comprehensive services from the early stages of product development to marketplace entry and ongoing compliance.